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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,194	12/01/2003	John Fitzgerald Kokai-Kun	7787.0061-00	1338

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LAHIVE & COCKFIELD
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BOSTON, MA 02109

EXAMINER

PORTNER, VIRGINIA ALLEN

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 02/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/724,194	Applicant(s) KOKAI-KUN ET AL.	
	Examiner Ginny Portner	Art Unit 1645	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-30, 39-58 is/are pending in the application.
- 4a) Of the above claim(s) 39-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-30 is/are rejected.
- 7) ☒ Claim(s) 26-27, 29-30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/2/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 18-30, 39-58 are pending.

Claims 18, 26-27, 29-30 have been amended.

Claims 39-58 remain withdrawn from consideration.

Response to Arguments

Objections/Rejections Maintained

1. ***Claim Objections Maintained:*** The objection to claims 26-27 and 29-30 to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim is traversed on the grounds that the claims have been amended to “inhibits or prevents a staphylococcal infection” and based upon these claim amendments the objection is requested to be withdrawn.
2. It is the position of the examiner that the components present in the composition of claim 18 and claims 26-27 and 29-30 are the same. While claims 26-27 and 29-30 no longer broaden the scope of claim 18, they do not further limit the scope of claim 18, as the claimed compositions are identical; there are no structural differences claimed between claim 18 and claims 26-27 and 29-30. A recited intended use of a claimed composition is not further limiting of the structural components of a claimed composition. While the specification can be used to provide definitive support, the claims are not read in a vacuum. Rather, the claim must be definite and complete in and of itself. Limitations from the specification will not be read into the claims. The claims as they stand are incomplete and fail to provide adequate structural properties to allow for one to identify what is being claimed. Claims 26-27 and 29-30 are still not further limiting of independent claim 18.

1. ***Claim Rejections - 35 USC § 102 Maintained:*** The rejection of claims 18-30 under 35 U.S.C. 102(b) as being anticipated by Fischer et al (WO98/57994) as evidenced by (PG Pub 20030228322A1) is traversed on the grounds that the wall teichoic acid of S.aureus is distinct and an entirely different molecule with a different chemical structure from that of S. epidermidis, wherein the WTA claimed has a ribitol phosphate structure.

2. The Examiner agrees that wall ribitol teichoic acid and wall glycerol teichoic are structurally different molecules, but the claimed invention is not limited in scope to only encompass antibodies that will bind to wall ribitol teichoic acid, but is directed to a pharmaceutical compositions: that comprises antibodies that will “specifically bind to wall teichoic acid of S.aureus”. The scope of the instantly claimed invention is directed to a genus of antibody compositions that will bind to the wall teichoic acid of any S. aureus strain or species.

At page 28, [061-063] of the instant Specification, Applicant defines the claimed invention to include antibodies that immunocross react with Listeria monocytogenes and S. epidermidis and therefore include antibodies directed to both types of wall teichoic acid, which includes antibodies directed to wall glycerol teichoic acid (Instant Specification, [061 “The cell walls of Gram positive bacteria seem much simpler in comparison, containing two major components, peptidoglycan and teichoic acids plus additional carbohydrates and proteins depending on the species”]).

1. Upon consideration of S. aureus wall teichoic acids known in the art, the Examiner considered:

- Endl et al (1983, reference submitted in Applicant’s US-PTO 1449) who evaluated the “Chemical Composition and structure of cell wall teichoic acids of staphylococci

(title)”, and documented 5 strains of *S. aureus* that present glycerol teichoic acid in their cell walls (see Table 1, page 217, and “b” footnote).

- Vinogradov et al (2006) found *Staphylococcus aureus* MN8m, a biofilm forming strain, to produce *two polymers*, in the wall teichoic acid region, one of which is “poly(glycerol) phosphate (see abstract; also see Figure 4 and Table 2 of page 4)”.
- US Patent 6,703,025 (detailed Description paragraph 95) teach teichoic acids, and lipoteichoic acids are polymers of glycerol or ribitol phosphate and are linked to the peptidoglycan and can be antigenic. Antiteichoic antibodies are detectable by gel diffusion in patients with active endocarditis due to *S. aureus* infection.
- Gargir et al (2001) shows anti-polyglycerol phosphate antibodies to assist in the induction of significant amounts of IL-6 when combined with *S.aureus* cells in the presence of macrophages (see abstract). The reference teaches “Lipoteichoic acids (LTA) are components of the cell membrane cell walls of virtually all Gram-positive bacteria, and they can also be secreted into the surrounding milieu.”

Therefore, the scope of the instantly claimed invention encompasses antibodies directed to both glycerol teichoic acid, ribitol teichoic acids, as well as the carbohydrates associated with the teichoic acid polymers presented by *S.aureus* based upon Applicant’s definitions provided in the instant Specification and the fact that *S.aureus* is known to produce both glycerol phosphate and ribitol phosphate WTA.

The antibodies disclosed in Fischer et al are antibodies that would and will bind to WTA of *S. aureus* ((see Fischer et al, page 9, paragraph 2, last sentence: surface exposed) . The Fischer et al antibodies were shown to specifically bind to not only (see page 24) “*S.epidermidis*,

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strain Hay” but also to *S. aureus* 5 and *S. aureus*-8 (see page 27, bottom of page and page 28, paragraphs 1-2; also see Table 6, Table 8, Table 9).

2. Applicant points to paragraph [0034] of the instant Specification and to Weidenmaier et al, Nature Medicine 2004 to show a ribitol phosphate WTA structure, and concludes that because the LTA of Fischer is structurally different from ribitol phosphate WTA, the antibodies of Fischer et al would not specifically bind to the WTA of *S. aureus* and asserts that the antibodies cannot anticipate the claimed WTA antibodies.

3. It is the position of the examiner that the instantly claimed WTA antibodies include antibodies directed to ribitol phosphate teichoic acid, AND glycerol phosphate teichoic acid because *S. aureus* is known in the art to produce both types of cell wall teichoic acid (see Endl et al and Vinogradov et al) and not just ribitol phosphate teichoic acid as asserted by Applicant. Applicant's traversal is not commensurate in scope with the instantly claimed invention that is defined in the instant Specification at a number of locations ([061-063]) to include antibodies that are cross-reactive to other gram-positive bacteria, and to immunoreact with any type of wall teichoic acids ([061]).

4. While the claims have been amended to recite *S. aureus*, the antibodies claimed must functionally “block staphylococcal colonization”, which includes strains and species of *Staphylococcus* that need not be *S. aureus*. Clearly the claims are directed to a genus of antibodies that must specifically immunoreact to block “staphylococcal colonization”. The source of immunogen being *S. aureus* (amended claims), but the antibodies must block or may block a plurality of staphylococcal infection causing strains and species and is not limited to

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antibodies that only immunoreact and block colonization caused by S.aureus because S.aureus WTA is known to comprise either glycerol phosphate teichoic acid or ribitol phosphate teichoic acid or both (see Endl et al and Vinogradov et al cited above) and antibodies directed to glycerol phosphate teichoic acid are disclosed in the applied reference, Fischer et al. Fischer et al still anticipates the instantly claimed invention as now claimed.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
February 13, 2006


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